Michigan Department of Agriculture

Training Program for the Professional Food Service Sanitarian

Module 9: Introduction to Food Labeling

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What is NLEA ?

NLEA is the Nutrition Labeling and Education Act of 1990. This law provides FDA with specific authority to require nutrition labeling of most foods regulated by the Agency; and to require that all nutrient content claims (i.e., high fiber, 'low fat', etc. and health claims), be consistent with agency regulations. Regulations implementing the NLEA labeling provisions were issued on January 6, 1993 and became effective on August 8, 1994 (percent juice labeling was subsequently exempted until May 8, 1994).

Basics of Food Labeling

The requirements for nutrition labeling are detailed in the regulations issued in January 1993 by FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (FDIS).

The label must include "Nutrition Facts" (see appendix 1). The mandatory **(underlined)** and voluntary dietary components and order in which they must appear are:

- Total calories
- calories from saturated fat
- total fat
- saturated fat
- stearic acid (on meat and poultry products only)
- polyunsaturated fat
- monounsaturated fat
- cholesterol
- sodium
- potassium
- total-carbohydrate
- dietary fiber
- soluble fiber
- insoluble fiber
- sugars
- sugar alcohol (for example, the sugar substitutes xylitol, mannitol and sorbitol)

- other carbohydrates (the difference between total carbohydrate and the sum of
- dietary fibers, sugars and sugar alcohol, if declared.
- Protein
- vitamin A
- percent of vitamin A present as betacarotene
- Vitamin C
- Calcium
- iron
- other essential vitamins and minerals

Appendix 1

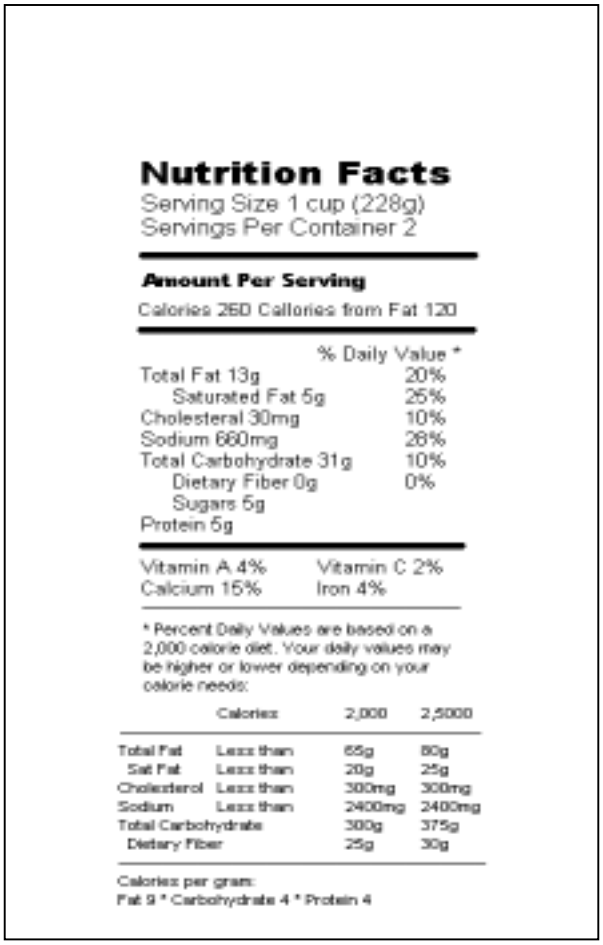
Consistent serving sizes, in both houshold and metric measures.

Nutrients required on nutrition panel are those most important to the health of today's consumers, most of whom need to worry about getting too much of certain items (i.e. fat), rather than too few vitamins or minerals, as in the past.

% Daily Value shows how a food fits into the overall daily diet

Reference values help consumers learn good diet basics. They can be adjusted, depending on a person's calorie needs.

Conversion guide helps consumers learn caloric value of the energy producing nutrients.



Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value *
Total Fat 13g	20%
Saturated Fat 5g	25%
Cholesteral 30mg	10%
Sodium 660mg	28%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	

Vitamin A 4%	Vitamin C 2%
Calcium 15%	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,5000
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2400mg	2400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 * Carbohydrate 4 * Protein 4

If a food is fortified or enriched with any of the optional components, or if a claim is made about any of them, the pertinent nutrition information then becomes mandatory. These mandatory and voluntary components are the only ones allowed on the nutrition panel. The listing of single amino acids, maltodextrin, calories from polyunsaturated fat, and calories from carbohydrate, for example, may not appear on the label. Too much additional information could clutter the label and mislead or confuse the consumer. Nutrients required on the label reflect current public health concerns and coincide with public health recommendations.

The Food Label displays many of the macronutrients (such as fat, cholesterol, sodium, carbohydrate, and protein) to be declared as a percent of the Daily Value - a new label reference value. The amount, in grams or milligrams per serving, of these nutrients still must be listed to their immediate right. A column headed `%Daily Value" will appear. The percent declaration of the Daily Value offers an advantage over amount declaration: The Daily Values put the nutrients on equal footing in the context of a total diet. A food is low in sodium if it has less than 140 mg of sodium. " 140 mg. of sodium is less than 6 percent of the Daily Value." But a consumer could confuse 5g of saturated fat as being low in that nutrient because 5 is a small number. In reality, that food would provide one-fourth the total Daily Value of 20g of saturated fat for a 2,000-calorie diet. As a quick guide, a % Daily Value of 5% or less indicates that a food supplies a small amount of a nutrient, while a % Daily Value of 20% or more indicates a large amount.

The percent Daily listing will carry a footnote stating that the percentages are based on a 2,000-calorie diet and that a person's individual dietary goal is based on his or her calorie needs. The calorie conversion information may be voluntarily indicated as a general guide about the caloric contributions of fat, carbohydrate and protein.

Foods for children under 2 (except infant formula, which is exempt from nutrition labeling under NLEA) do not carry information about calories from fat, calories from saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol. This will prevent parents from inadvertently assuming that infants and toddlers should restrict their fat intake, when in fact, they should not. Fat is important during this life stage to ensure adequate growth and development.

The labels of food for children under 4 cannot include percentages of Daily Values for macro nutrients for this age group because daily reference amounts have not been established. The percent Daily Values for vitamins and minerals is allowed but the content of the other nutrients must be

expressed as an amount by weight in a separate column to the right of the macro nutrients.

The serving size remains the basis for reporting each nutrient's amount. The serving sizes represent the amounts that many people actually eat. They also must be expressed in both common household and metric measures (see appendix 2).

Appendix 2

Metric Conversion Chart

Units as they will appear for serving sizes on label

Household Measure	Metric Measure
1 tsp	5 mL
1 tbsp	15 mL
1 cup	240 mL
1 fl oz	30 mL
1 oz	28 g

tsp = teaspoon

tbsp = tablespoon

fl oz = fluid ounce

oz = ounce

mL = mililiter

g = gram

Nutrient Content Claim

Food Labeling Regulations spell out which nutrient content claims are allowed and under what circumstances they can be used. There are 11 core terms:

- free
- low
- lean
- extra lean
- high
- good source
- reduced
- less
- light
- fewer
- more

The regulations allow manufacturers the option to use the following synonyms for
the term "free":

- without
- trivial source of
- negligible source of
- dietarily insignificant source of
- no
- zero

Whatever term the manufacturer chooses, the product must either be absolutely free of the nutrient in question or, if the nutrient is in the food, the amount must be dietetically trivial or physiologically insignificant.

For example, zero fat cannot be required because it is impossible to measure below a certain amount. So, the regulation will allow a fat-free claim on foods with less than 0.5 grams(g) of fat per serving, an amount that is physiologically insignificant even if a person eats several servings.

Foods that don't contain a certain nutrient naturally must be labeled to indicate that all foods of that type meet the claim. For example, a fat-free claim on applesauce would have to read "applesauce, a fat-free food." "Free" also can be used in reference to saturated fat, cholesterol, sodium, sugars, and calories.

A food meets the definition for "low" if a person can eat a large amount of the food without exceeding the Daily Value for the nutrient (see appendix 3).

Appendix 3

Daily Values for Nutrition Labeling

(Based on 2,000 calorie intake for adults and Children 4 or more years of age)

Nutrients in this table are listed in the order in which they are required to appear in accordance with 101.9(c)

This list includes only those nutrients for which a Daily Reference Value (DRV) has been established in 101.9(c)(9) or a Reference Daily Intake (RDI) in 101.9(c)(8)(iv).

NUTRIENT	M or V	UNIT OF MEASURE	DAILY VALUE
Total Fat	M	Gram (g)	65
Saturated Fatty Acids	M	Gram (g)	20
Cholesterol	M	Milligrams (mg)	300
Sodium	M	Milligrams (mg)	2400
Potassium	V	Milligrams (mg)	3500
Total Carbohydrate	M	Gram (g)	300
Dietary Fiber	M	Gram (g)	25
Protein	M	Gram (g)	50
Vitamin A	M	International Unit (IU)	5000
Vitamin C	M	Milligrams (mg)	60
Calcium	M	Miligram (mg)	1000
Iron	M	Milligrams (mg)	18
Vitamin D	V	International Unit (IU)	400
Vitamin E	V	International Unit (IU)	30
Thiamin	V	Milligrams (mg)	1.5
Riboflavin	V	Milligrams (mg)	1.7
Niacin	V	Milligrams (mg)	28
Vitamin B3	V	Milligrams (mg)	2.0
Folate	V	Milligrams (mg)	0.4
Vitamin B12	V	Micrograms	6
Biotin	V	Milligrams (mg)	0.3
Pantethenic acid	V	Milligrams (mg)	10
Phosphorus	V	Miligram (mg)	1000
Iodine	V	Micrograms	150
Magnesium	V	Milligrams (mg)	400
Zinc	V	Milligrams (mg)	15
Copper	V	Milligrams (mg)	2.0
Manganese	V	Milligrams (mg)	2.0

NUTRIENT	M or V	UNIT OF MEASURE	DAILY VALUE
Chromium	V	Micrograms	120
Molybdenum	V	Micrograms	75
Chloride	V	Milligrams (mg)	3,400
M = Mandatory V = Voluntary			

The synonyms allowed for "low" are:

- little
- few
- contains a small amount of
- low source of

"Low" claims can be made in reference to total fat, saturated fat, cholesterol, sodium, and calories. A claim of "very low" can be made only about sodium.

"Lean" and "extra lean" can be used to describe the fat content of meat, poultry, seafood, and game meats. (FSIS regulates meat and poultry products; FDA oversees seafood and game meats.) "Lean" means the food has less than 10g of fat, 4.5g or less of saturated fat, and less than 95 milligrams (mg) of cholesterol per serving and per 1 00g. An example of a serving is 55g (2oz.) for fish, shellfish or game meat. Some "lean" foods are Spanish mackerel, bluefin tuna, and domesticated rabbit.

"Extra lean" means the food has less than 5g of fat, less than 2g of saturated fat, and less than 95mg of cholesterol per serving and per 100g. Examples of "Extra lean" foods are haddock, swordfish, clams, and deer.

FDA and FSIS believe that a claim implies, and consumers expect, that the products bearing the "percent fat free" claim contains relatively small amounts of fat and is useful in maintaining a low-fat diet. Therefore, products with these claims must meet the definitions for low fat. In addition, the claim must accurately reflect the amount of fat present in 100g of food. For example, if a food contains 2.5g of fat per 50g, the claim must be "95 percent fat free".

"High" and "good source" claims focus on nutrients for which higher levels are desirable. To qualify for the "high" claim, the food must contain 20 percent or more of the Daily Value for the nutrient in a serving. Approved synonyms for high are "rich in" or “excellent source." "Good source" means a serving contains 1 0 to 19 percent of the Daily Value for the nutrient.

Manufacturers who want to compare a nutritionally altered product with the regular product may make a relative claim-that is, "reduced," "less," "fewer," “more", or "light". The regular products, or reference foods, may be either an individual food or a group of foods representative of the type of food, for example, an average of three market leaders.

Restrictions on these claims and reference foods include:

*A relative claim must include the percent difference and the identity of the reference food.
*"Reduced," "less" and "light" claims can't be made on products whose nutrient level in the reference food already meets the requirement for a "low" claim.

*Reference foods for "light" and "reduced" claims must be similar to the product bearing the claim, for example, reduced fat potato chips compared with regular potato chips.

*Reference foods for "less" and, in the case of calories, "fewer" may use dissimilar products within a product category, for example, pretzels with 25 percent less fat than potato chips.

A serving of a food carrying a "more" claim (or claims of fortified, enriched or added), must have at least 1 0 percent more of the Daily Value for a particular nutrient (that is, dietary fiber, potassium, protein, or an essential vitamin or mineral), than the reference food that it resembles.

A "health claim" is any claim on the package label or other labeling of a food, including fish and game meats, that characterizes the relationship of any nutrient or other substance in food to a disease or health-related condition. An example of a health claim is, "A diet low in total fat may reduce the risk of some cancers." This claim associates the two necessary components: a specific nutrient or food substance and a specific health problem.

Health claims include implied claims, which indirectly assert a relationship. Implied claims may appear as third-party references, such as "The National Cancer Institute recommends a high-fiber diet." Brand names (such as "Heart Smart"), symbols (such as heart-shaped logos), and specific nutrient information, may within the context of the label result in a health claim.

To qualify for labeling with a health claim, foods must contain:
*a nutrient (such as calcium) whose consumption at a specified level as part of an appropriate diet will have a positive effect on the risk of disease or

*a nutrient of concern (such as fat) below a specified level.

The food must contribute nutrition to the diet by containing at least IO percent of the Daily Value (D.V.) of one or more of the nutrients vitamin A, vitamin C, iron, calcium, protein, and fiber. These nutrients must occur naturally in the food at least at 10 percent of the Daily Value. NLEA specifies that foods bearing health claims must not contain any nutrient or food substance in an amount that increases the risk of a disease or health condition.

Exemptions and Special Labeling Provisions [(21 CFR 101.9 (j)]

A product is exempt from nutrition labeling if no nutrition information is declared on the label or labeling, if no nutrient content or health claim is made and if the manufacturer/packer or distributor meets one or more of the following provisions:

- Small Business Exemption based on value of gross sales (Note: this exemption based on value of gross sales will apply only to retailers).

  For foreign firms importing foods, this exemption is based on the total amount of sales to consumers in the United States. The product is exempt from nutrition labeling if the firm whose name appears on the label has annual gross sales of food to consumers of not more than $50,000; or has total annual gross sales to consumers of not more that $500,000.

- Small Business Exemption for low volume food products based on the average number of full time equivalent employees (FTE's) and approximate units (of sale) of food products sold in the United States. To obtain this exemption, a firm must notify FDA annually.

  (NOTE: a firm with less than 1 0 employees and less than 1 0,000 units does not have to notify FDA for an exemption).

  Foods are exempt from the nutrition labeling providing the firm has fewer than 100 FTE's and less than 1 00,000 units were sold in the previous year.

  New food products are exempt providing the firm has fewer than 100 FTE's and less than 100,000 units are projected for marketing in the first 12 months.

- **Foods served or sold in restaurants are exempt unless a nutrition claim is made on or about the food (e.g., fat free salad dressing). In such a case, nutrition labeling must be in compliance. See section VII of this module.**

- Foods served and sold for immediate consumption (e.g., schools, cafeterias, trains, airplanes, and retail stores, such as bakeries and deli's) where there are facilities for immediate consumption.

- Foods that are not for immediate consumption, that are processed and prepared primarily in a retail establishment and not offered for sale outside that establishment (e.g., bakeries and deli's).

- Foods that are not for immediate consumption and are not processed or prepared on the premises, but are packaged and portioned on a consumer's request.

- Foods that contain insignificant amounts of all nutrients required to be listed in nutrition labeling (e.g., coffee and most spices).

  - Infant formula subject to the Infant Formula Act.

  - Dietary supplements of vitamins and minerals not in conventional food form must comply with the requirements of 101.36.

  - Medical Foods.

  - Bulk foods for further manufacturing or repacking.

  - Raw fruits, vegetables, and fish (covered by voluntary program for display at retail level; however, when a claim is made, nutrition information must be displayed by the retailer).

    One key to the inclusion of fish in the voluntary program is that the product, as sold to the consumer, is packaged at the retail establishment. In ' addition, raw shellfish, in or out of the shell is under the voluntary program; as is refrigerated or iced pasteurized crab meat that is not shelf-stable.

- Custom processed fish and game meat. All game meats may provide separate nutrition information on labeling instead of on labels.

- Foods in packages with available label space of less than 12 square inches (e.g., pack of gum), provided that the label provides a means for consumers to obtain nutrition information (e.g., address, phone number).

- Food sold from bulk containers, provided that nutrition information is . provided at point of sale.

- Shell eggs packed in a carton that has a top lid designed to conform to the shape of the eggs are exempt from outer carton label requirements when the required information is presented inside the carton lid or in an insert. The agency does not object to presenting the required nutrition label inside the lid of any egg carton.

- FOODS FOR INFANTS AND CHILDREN LESS THAN 4 YEARS OF AGE
  Nutrient names and quantitative amounts must be presented in two separate columns. Also, percent Daily Values may only be listed for protein, vitamins and minerals. The footnote is prohibited.

  FOODS FOR INFANTS AND CHILDREN LESS THAN 2 YEARS OF AGE
  In addition to the referenced restrictions for children less than 4; foods intended for children less than 2 years of age may not list calories from fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol in nutrition label.

FDA Labeling Policy for Foods Requiring Refrigeration by Consumers

To clarify this guidance, the agency has delineated each of the three groups and developed model statements for each:

1. Group A Foods - Group A foods are potentially hazardous foods, which if subjected to temperature abuse, will support the growth of infectious or toxigenic microorganisms that may be present. Outgrowth of these microorganisms would render the food unsafe. Foods that must be refrigerated for food safety possess the following characteristics:

    - product pH > 4.6;
    - water activity a >0.85;
    - do not receive a thermal process or other treatment in the final package
    - that is adequate to destroy foodborne pathogens which can grow under conditions of temperature abuse during storage and distribution, and
    - have no barriers (for example, preservatives such as benzoates, salt, acidification), built into the product formulation that prevent the growth of foodborne pathogens that can grow under conditions of temperature abuse during storage and distribution.
    - The appropriate label statement for Group A foods is:

IMPORTANT
Must Be Kept
Refrigerated
To Maintain Safety

2. Group B Foods - Group B includes those foods that are shelf-stable as a result of processing, but once opened, the unused portion is potentially hazardous unless refrigerated. These foods possess the following characteristics:

   - product pH > 4.6;

   - water activity a > 0.85;

   - receive a thermal process or other treatment that is adequate to destroy or inactivate foodborne pathogens in unopened package, but after opening, surviving or contaminating microorganisms can grow and render the product unsafe; and

   - have no barriers (for example, preservatives such as benzoates, salt, acidification) built into the product formulation to prevent the growth of foodborne pathogens after opening and subsequent storage under temperature abuse conditions.

     The appropriate label statement for Group B foods is:

IMPORTANT
Must be Regrigerated
After Opening
To Maintain Safety

3. Group C Foods - Group C are those foods that do not pose a safety hazard even after opening if temperature abused but may experience a more rapid deterioration in quality over time if not refrigerated. The manufacturer determines whether to include on the label a statement that refrigeration is needed to maintain the quality characteristics of the product to maximize acceptance by the consumer. These foods do not pose a safety problem. Foods in this group possess one or more of the following characteristics to assure that the food does not present a hazard if temperature abused:

   - product pH< 4.6 to inhibit the outgrowth and toxin production of C. botulffinum; or

   - water activity a < 0.85; or

   - have barriers built into the formulation (for example, preservative systems such as benzoates, salt, acidification) to prevent the growth of foodborne pathogens if the product is temperature abused:

   The suggested optional label statement for Group C foods is :
   Refrigerate for Quality or some other statement that explains to the consumer that the storage conditions are recommended to protect the quality of the product. To avoid confusion between refrigeration for safety purposes and refrigeration for quality reasons, Group A and Group B statements should not be used on Group C foods.

Label Declaration of Allergenic Substances in Foods

Recently, FDA has received increased numbers of reports of adverse reactions following exposure to an allergenic substance in foods. These exposures occurred because the presence of the allergenic substance in the food was not declared on the food label.

The Food , Drug, and Cosmetic Act (the act) requires, in virtually all cases, a complete listing of all the ingredients of a food. Two of the very narrow exemptions from ingredient labeling requirements appear to have been involved in a number of the recent incidents, however. First, section 403(i) of the act provides that spices, flavorings, and colorings may be declared collectively without naming each one. Secondly, FDA regulations (21 CFR 101.100 (a) (3)) exempt from ingredient declaration incidental additives, such as processing aids, that are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food.

In some of the instances of adverse reactions, failure to declare an ingredient appears to have been the result of a misinterpretation of the exemption from ingredient declaration provided for incidental additives in §101.100 (a) (3). FDA reminds manufacturers that to qualify for the exemption from ingredient declaration provided for incidental additives and processing aids, a substance must meet both of the requirements of § 101.100 (a) (3), i.e., it must be present in the food at an insignificant level, and it must not have any technical or functional effect in the finished food. Thus, incidental additives may include substances that are present in a food by virtue of their incorporation as an ingredient in another food. However, when an ingredient added to another food continues to have an effect in the finished food (e.g., egg white as a binder in breading used on a breaded fish product), the ingredient is not an incidental additive, and its use must be declared on the label.

The recent adverse reaction reports indicate that some manufacturers have also incorrectly interpreted what constitutes an insignificant level of a substance. Clearly, an amount of a substance that may cause an adverse reaction is not insignificant. Because evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts of the substance, it is unlikely that such an allergen, when it is present in a food, can be present at an insignificant level. Thus, it follows that the requirements of § 1 01. 1 00 (a) (3) can not be met under such circumstances.

FDA is considering whether it is necessary to clarify its regulations to ensure that manufacturers fully understand the circumstances in which allergenic food ingredients must be declared and to ensure that sensitive individuals are protected by appropriate labeling.

FDA has also received reports of adverse reactions to foods in which likely allergenic substances were used as flavors, and not declared by name. Therefore, in addition to the exemption in § 101.100 (a) (3), the agency is also considering whether an allergenic ingredient in a spice, flavor, or color should be required to be declared, 403 (i) not withstanding. On a substance-by-substance basis, the agency has required ingredients covered by the exemption in section 403 (i) to be declared when necessary to protect individuals who experience adverse reactions to the substance, e.g., FD&C Yellow No.5 The agency is open to suggestions on how to best address this problem.

While FDA has not formally defined "allergens," it provided examples of foods that are among the most commonly known to cause serious allergenic responses, i.e., milk, eggs, fish, crustacean mollusks, tree nuts, wheat, and legumes (particularly peanuts and soybeans), in a policy statement dealing with foods derived from new plant varieties published in the FEDERAL REGISTER of May 29,1992 (57 FR 22984 at 22987).

FDA advises that the issue of declaring allergenic ingredients in food is being discussed on an international level. Several individual governments and the Codex Alimentarius Commission have begun to formulate policy for the labeling of foods containing allergenic ingredients to ensure that consumers are provided sufficient information to avoid substances to which they are allergic. While packaged foods sold in the U.S. are among the most comprehensively labeled foods in the world (some countries provide broader exemptions from ingredient declaration), FDA is studying its labeling requirements, and considering whether rule making is necessary, for the labeling of allergenic ingredients.

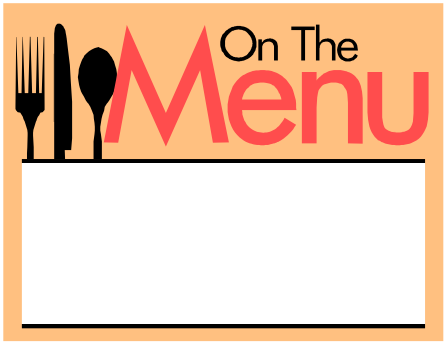
While the agency does so, FDA asks manufacturers to examine their product formulations for ingredients and processing aids that contain known allergens that they may have considered to be exempt from declaration as incidental additives under § 101.100 (a) (3), and to declare the presence of such ingredients in the ingredient statement. Where appropriate, the name of the ingredient may be accompanied by a parenthetical statement such as "(processing aid)" for clarity.

The voluntary declaration of an allergenic ingredient of a color, flavor, or spice could be accomplished by simply naming the allergenic ingredient in the ingredient list. Because such ingredients are normally present at very low levels, the name of the ingredient could generally be placed at the end of the list and be consistent with its descending order of predominance by weight. Other, nonallergenic ingredients that are exempt from declaration would remain unlisted.

Another area of concern is the potential, inadvertent introduction of an allergenic ingredient to a food (e.g., in a bakery that is manufacturing two food products on one production line, one product with peanuts and one without, where traces of peanuts, or peanut products, may end up in the product that does not normally contain peanuts). FDA is considering options for providing consumers with information-about the possible presence of allergens in these foods.

The agency is also aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (insert name of allergenic ingredient)." FDA advises that because adhering to good manufacturing practices (GMPs) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMPs. The agency urges manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of the identified food. The agency is open to suggestions on how best to address this issue.

Nutrition Information On Restaurant Menus



The Food and Drug Administration set standards for the claims that can be made in restaurant menus for the nutritional values of individual foods and meals to ensure that consumers get what they order (21 CFR 101.10).

This final rule means that if claims like "low fat' or 'heart healthy" are made on a restaurant menu, the restaurant owner must be able to demonstrate that there is a reasonable basis for believing that the food qualifies to bear this claim.

The rule allows restaurants considerable flexibility in establishing this reasonable basis and in presenting the information to consumers.

This final rule affects only those Restaurants who place claims such as "low fat" or 'heart healthy" on their menus. These restauranteurs must be prepared to show officials that their menu claims are consistent with the claim definitions established under the Nutrition Labeling and Education Act of 1990 (NLEA)-

Unlike processed foods, restaurant menu selections are not required to supply . complete nutrition information. Also, unlike processed foods, menu items bearing a claim are not held to the same strict standard of laboratory analyses. Other more economical methods can be used to meet the standard. For example, a restaurant could show that the item was designed to meet the requirements for the claim by preparation using a recipe from a recognized health professional association or dietary group, or calculation of the nutritional values of the dish using a reliable nutrition data base.

Furthermore, nutrition information can be provided to the consumer by any reasonable means. It does not have to be presented in the "Nutrition Facts" format seen on packaged food labels, nor does it have to appear on the menu. A restaurant

for example, may compile in a notebook information on the fat content of all menu items that bear fat claims so long as the nutrition information is available to consumers upon request.

FDA estimates that the rule's flexibility and this limited scope should minimize its economic impact on the restaurant industry.

Restauranteurs seeking guidance for complying with new menu regulations can consult the sections of FDA's August 1995 guidance on food labeling that deal with claims on restaurant signs and placards. Copies of this document, "Food Labeling Questions and Answers, Volume 2 -- A Guide for Restaurants and Other Retail Establishments" can be obtained through the Superintendent of Documents, U.S. Government Printing Office, Washington,D.C. 20402, (202) 512-1800 and is alos available on the FDA's website (http://www.fda.gov/).

The U.S. District Court of Washington, D.C. on June 28, 1996, . ordered FDA to finalize regulations for restaurant menu labeling. The court issued its decision in response to a lawsuit filed by consumer groups seeking to include restaurant menus under the provisions of NLEA. The Court agreed with the plaintiff s argument that the NLEA specifically required that restaurants could only make nutritional and health claims that were consistent with FDA regulations.

References & Audiovisual Resources List

References

Questions and Answers , Volumes 1 and 2, Office of Nutritional Products Labeling & Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C. St. SW., Washington, DC 20204. (http://www.fda.gov/)

FDA Consumer, Department of Health & Human Services

DHHS PUBLICATION NO. (FDA) 93-2262

A Food Labeling Guide, Office of Nutritional Products Labeling & Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C. St. SW., Washington, DC 20204. (http://vm.cfsan.fda.gov/~dms/flg-toc.html)

Audio Visual Resource List

Label-Ease " A Guide to Using the New Food Labels" This 12 minute interactive video literally gives you hands-on training. It will teach you to evaluate the nutrient density of a food using just the fingers on one hand and the new food labels. This video is available for purchase from the "Dairy Council of the Upper Midwest", 2015 Rice Street, St. Paul, Minnesota 55113. Phone: (612) 488-026 - Fax: (612) 488-0265

Food Labeling At a Glance - This video describes basic food labeling requirements.

This video is available for purchase from " Florida Cooperative Extension Service", 3002 McCarty Hall University of Florida, Gainesville, Florida 32611-0130. Phone (904) 392-7087

Additional Resource Material Available

FDA Food Enforcement Handbook (Second Edition), prepared by the staff of Food Chemical News. The book has all the compliance and Enforcement Policies on all food related issues including food labeling. It is available for purchase by calling (202) 5441980.

Food and Dairy Division Food Labeling Guide

For Products Manufactured or Sold in Michigan

The Food and Dairy Division of the Michigan Department of Agriculture is responsible for assuring that foods and other consumer packages are properly labeled. The Michigan Food Law of 1968, PA 39 of 1968; the Michigan Weights and Measures Law, PA 283 of 1964; and Regulation No. 551, the Weights, Measures, Packaging, and Labeling Regulation are the primary Michigan laws governing food labeling.

This guide summarizes general labeling requirements for food products. In a leaflet such as this, it is impractical to attempt to answer every food labeling question that may arise. To help minimize regulatory action and delays, it is recommended that manufacturers and distributors become fully informed about the applicable labeling laws before offering food for distribution in Michigan.

DEFINITIONS:

- **The PRINCIPAL DISPLAY PANEL (PDP)** is the portion of the package that is most likely to be seen by the consumer at the time of purchase. The product identity and the declaration of quantity must appear on the PDP. All other required information may be placed either on the PDP or the information panel.

- **The INFORMATION PANEL** is generally the label panel immediately to the right of the PDP, as seen by the consumer facing the product (a few exceptions exist for irregular-size packages-refer to 21 CFR § 101.2).

SUMMARY OF THE BASIC REQUIREMENTS:

1. **THE STATEMENT OF IDENTITY**: (the product identity) must be the common or usual name of the food, if it has one. It would be misleading to label a food with a new name when that food has an established name. If no common or usual name exists, then an appropriately descriptive phrase must be used; the phrase must accurately describe the basic nature of the food or its characterizing ingredients or properties. If the food is subject to a standard of identity, it must bear the name specified in the standard.

The statement of identity must appear on the principal display panel in lines generally parallel to the base of the package. It must be prominent and of a type size reasonably related to the most prominent printed matter on the front panel; generally, this means at least one-half the size of the largest print on the label.

A. **ARTIFICIALLY FLAVORED**: When artificial flavorings are used that simulate, resemble, or reinforce the characterizing flavor of food, the product name must be accompanied by the phrase "artificially flavored" or "artificial" in type not less than one-half the size of the name of the food; for example, "Artificial Orange Flavored Punch" or "Artificially Flavored Strawberry Cheesecake" [21 CFR § 101.22].

B. **ARTIFICIALLY SWEETENED**: Beverages that contain artificial sweeteners shall be identified as "artificially sweetened" in letters not less than one-half the height of the other words in the product identity [R 285.549.21].

C. **FANCIFUL TERMS**: Fanciful terms are not encouraged since they are often confusing to the consumer. However, they may be used as a supplement to a proper statement of identity and are in no way false or misleading. For example, a label may read "Belly Bomber Ham & Cheese Sandwich" (but not "Belly Bomber" by itself).

D. **FORM OF THE FOOD**: Where a food is marketed in several forms (sliced, diced, whole, etc.), the particular form must be part of the identity statement [21 CFR § 101.3 (c)].

E. **IMITATION**: A food that is an imitation of another food must be labeled, in type of uniform size and prominence, with the word "imitation" immediately followed by the name of the food imitated [MCLA 289.717 (c)]. Any product that resembles and substitutes for a traditional food and contains less nutritional value than the traditional food is considered to be an imitation [21 CFR § 101.3 (e)(1)].

2. **NAME AND ADDRESS OF A RESPONSIBLE PARTY**: Must be declared as a unit and not separated by other label information. The address must include street address, city, state, and zip code. However, if the street address is listed in a current city or telephone directory under the responsible party name, the street address may be omitted on the label. If the responsible party is other than the manufacturer, the name must be qualified by a term describing the relationship to the product [MCLA 289.717 (e), R285.551.13, and 21 CFR § 101.5].

3. **QUANTITY DECLARATION**: Must be placed on the principal display panel (PDP) in the lower third of the panel. It must be printed in the required minimum type size and surrounded by sufficient clear space. The size of the statement is regulated by the area of the PDP [R285.551.42-43].

METRIC DECLARATION: Both metric and inch/pound measures must be declared in the net quantity statement. Either may be primary, for example, "Net wt I lb. (453 g)" or "Net wt 453 g (1 lb.)". This requirement for the net quantity statement to include metric units does not apply to foods packaged at the retail store level.

4. **INGREDIENT LIST**: A food product made from more than one ingredient must bear a complete list of ingredients in order of descending predominance by weight. Ingredients must be listed by their common or usual name. Spices and flavorings may be declared by the generic term "spices" or "flavorings" (artificial flavorings must be identified as artificial). The source of all fats and oils must be specified (for example, soybean oil rather than

vegetable oil; lard rather than shortening). Preservatives must have their function declared (for example, "preserved with sulfur dioxide").

A. **STANDARDS OF IDENTITY** specify in detail what can and cannot be sold under a certain product name. To a great extent, a standard of identity is a recipe f6r a food established by law, but it also prescribes ingredient labeling requirements and identification (naming) requirements. Examples of foods with standards of identities include bread, jams, jellies, preserves, cocoa, chocolate, and macaroni. Obtain specific federal standards of identity from the Superintendent of Documents (see page 5).

B. **COLORINGS**: All certified colors must be listed in the ingredient statement by their common name (e.g. FD&C Blue No. 1). Butter, cheese, and ice cream are exempt from this requirement except when it is necessary to assure safe use; i.e. FD&C Yellow No. 5. Non-certified and natural colors may still be listed by the generic term “colorings."

5. **TYPE SIZE**: All required information must be printed in a type size of at least 1/ 1 6-inch in height [21 CFR § 101.2 (c)]. Other specific requirements may apply which require type size larger than 1/ 16 inch, and all required information must be conspicuous and easy to read.

6. **NUTRITION FACTS**: As of May 8, 1994, nutrition labeling is required on most foods. Some foods exempt from nutrition labeling include restaurant food, food produced by small businesses, and food served for immediate consumption. However, use of any dietary or nutritional claim, such as "low fat," "diet," or "lean," forfeits any exemption from complete nutrition labeling.

The panel is headed by the title, "Nutrition Facts." The mandatory components and the order in which they appear are: total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron.

Serving size is the basis for reporting each food's nutrient content. In the past, choosing the serving size was up to the discretion of the food manufacturer. Serving sizes must now be based upon the FDA-established list of reference amounts.

The regulations also spell out what terms may be used to describe the level of a nutrient in a food and how they may be used. These definitions include the terms "light", "low", "reduced", "less", "more", and "high."

For more information on the new nutrition facts label, copies of the FDA Backgrounder, "The New Food Label" or "The New Food Label Summaries" are available from FDA.

7. **SELL BY DATE**: All packaged, perishable foods (those with a shelf life of less than 90 days) must be identified with a recommended last day of sale consisting of the month and day. Explanatory terms may also be used (such as sell by, sell before, last date of sale, or other meaningful terms). Color-coded twist ties or other non-date codes alone are not acceptable. Date coding is not required on perishable foods offered for sale from a vending machine, although it is encouraged [MCLA 289.713a and R285.554].

8. **MEANINGFUL CODING**: Packaged food distributed from a manufacturer, processor, packer, or re-packer, must have a meaningful code that enables positive lot identification [R285.553.22].

Other Special Considerations

- **BOTTLED WATER**: Bottled water must meet the labeling requirements of Sections 22a, 22d, 22e, and 22f of the Michigan Food Law, PA 39 of 1968, as amended. The label of each brand of bottled water with a unique identification must be registered with the Food and Dairy Division before the water is sold or offered for sale. Registration expires July 31 and must be renewed annually. Registration forms may be obtained from the MDA regional office nearest you.

- **MEATS AND MEAT PRODUCTS - USDA:** Persons planning to wholesale processed meat products (other than sandwiches), such as pizza pockets, meat pizzas, meat burritos, or meat egg rolls, must contact the U.S. Department of Agriculture (USDA) for labeling guidance. Generally, products containing more than 2 percent cooked meat/poultry (3 percent raw) fall under the jurisdiction of the USDA.

Additional Information

USDA/FSIS Compliance Offices

USDA/FSIS, Compliance Program 678 Front Ave. NW Suite 400 Grand Rapids, MI 49504 (616) 458-0915

USDA/FSIS, Compliance Program 25900 Greenfield Road Oak Park, MI 48237 (248) 968-0230

FDA Assistance

Businesses may submit labels directly to FDA for review. However, labels should be submitted to only one agency, either FDA or MDA. Requests to FDA may be submitted to the following office:

Food & Drug Administration
Center for Food Safety and Applied Nutrition
Division of Regulatory Guidance (HFF-3 10)
200 C Street, SW
Washington, D.C. 20204

The FDA District Office can also help a firm with labeling questions:

Compliance Branch (313) 226-6260
Food & Drug Administration
1560 East Jefferson Avenue
Detroit, MI 48207

Publications

The following publications contain more information about food laws and regulations. They may be obtained, for a fee, from the U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 152507954; Telephone: (202) 512-1800; Fax: (202) 512-2250. (Order by #)

Title 21, Code of Federal Regulations (CFR) contains the regulations that FDA enforces, including the nutritional labeling requirements. Those applicable to food labeling are:

Part I to 99 - General regulations for the enforcement of the Food Drug & Cosmetic Act and the Fair Packaging and Labeling Act. #869-019-00066-6

Part 100 to 169 Food Labeling, standards of identity, good manufacturing practices for foods, low-acid canned foods, and acidified foods. #869-019-00067-4 Part 170 to 199 Food Additives. #869-019-00068-2

Food Labeling - Questions and Answers contains detailed questions and answers especially on nutrition and labeling for guidance in the development or revision of labels. Send a written request with a self-addressed label to: Industry Activities Staff (HFS-565), Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, D.C. 20204

MDA LABEL REVIEW: Under laws enforced by MDA, no label approval is necessary prior to a product's distribution or importation. However, MDA will, upon request, review labels for compliance with Michigan law. This service is only available as resources permit. Our label review provides an informal opinion as to the acceptability of a label and in no way relieves a business from full responsibility for proper labeling. To avail yourself of this voluntary opportunity, submit all of the following: (1) the label or sketch, (2) specifications of the container's dimensions, and (3) the quantitative formula (recipe) to the regional office nearest you or (for out-of-state firms) Labeling Specialist, Food and Dairy Division, Michigan Department of Agriculture, P.O. Box 30017, Lansing, MI 48909.

MDA Regional Offices

UPPER PENINSULA: Room 126, State Office Building, Escanaba, MI 49829; (906) 786-5462

NORTHERN: 701 S. Elmwood, Suite 9, Traverse City, MI 49684; (231) 922-5210

WEST CENTRAL: State Office Bldg., 350 Ottawa, NW, Grand Rapids, MI 49503; (616) 356-0600

EAST CENTRAL: State Office Building; 411 F East Genesee, Saginaw, MI 48607; (517) 758-1778

SOUTHWEST: 4032 M-139, Building 116, St. Joseph, MI 49085; (616) 428-2546

SOUTH CENTRAL: P.O. Box 30017, Lansing, MI 48909; (517) 241-3306

DETROIT: Lahser Center, Suite 220,26400 Lahser Rd., Southfield, MI 48034; (248) 356-1700